

# Standard Operating Procedure CCTU/SOP005

## Test of Out of Hours Medical Cover Arrangements

### 1. Scope

This SOP applies to Chief Investigators (CIs) and Principal Investigators (PIs) within the Trust (either as substantive employees or under an honorary contract) involved with, or working on Trust sponsored Clinical Trials of Investigational Medicinal Products (CTIMPS).

### 2. Purpose

The purpose of this SOP is to describe the process that must be followed to ensure that appropriate medical care and advice on trial related matters is available at all times, including outside of normal working hours.

### 3. Definitions and Abbreviations

The headings below contain the definitions of terms and meaning of abbreviations used within the document.

Common abbreviations and definitions can be found in CCTU/INF001 Common Abbreviations and Definitions.

#### 3.1. Definitions

Term	Definition
Trust-Sponsored	Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH) or sponsored by CUH jointly with The University of Cambridge
Test Caller	A nominated independent individual who calls the contact numbers out of hours to validate the test plan

#### 3.2. Abbreviations

Abbreviation	Meaning
CI	Chief Investigator
PIS	Patient Information Sheet
PI	Principal Investigator
PID Card	Patient Identification Card

### 4. Undertaken by

The Principal Investigator (PI) responsible for the trial at a specific site, or staff delegated by PI to carry out the test. The Chief Investigator (CI) is responsible for ensuring that all participating sites have adequate medical cover arrangements in place for their trial.

## 5. Items Required

Site Specific Patient Information Sheet  
Site Specific Patient Identification Card (if appropriate/used)

## 6. Summary of Significant Changes

Not applicable. This is a new document.

## 7. Method

The following sections provide a description of the processes to be followed when implementing this document's procedures.

### 7.1. Use of Appropriate Contact Details

- The out of hours (emergency) contact details must be present in both the Patient Information Sheet (PIS) and Patient Identification (PID) Card
- The PI at each site is responsible for ensuring that the out of hours contact details provided to patients are suitable, correct and in compliance with their own Trust policies and procedures.

### 7.2. Testing the Out of Hours Medical Cover Arrangements

- Each out of hours phone number provided on the patient documents should be tested prior to recruitment of the first patient at that site.
- The local PI is responsible for selecting a member of staff at their site to carry out the out of hours testing (test caller).
- The test calls should be made outside of normal working hours (Monday to Friday 5.30pm – 9am, weekends and bank holidays).
- The test caller is responsible for making the telephone call(s) using the telephone numbers provided on the PID Card and PIS.
- The call is considered successful if the test caller is able to contact either:
  - a member of the trial team directly
  - an on-call member of the department who is able to locate details of the protocol/patient and provide suitable advice
  - a pager service and receive a call back from an appropriate member of the trial team or on-call team within a pre-determined (as defined by the Trust's/departments own policy) time limit
- The call should be considered unsuccessful if the test caller is:
  - Unable to make any contact on the telephone number (s) provided for any reason, including a wrong number or continuous ringing
  - Unable to contact anyone on the telephone number provided with access, understanding or experience of the trial or trial related documentation including patient medical records.
  - Call back is not within the pre-determined time limit (as defined by the Trust's/departments own policy)

- The outcome of the test call(s) should be recorded in a trial level file note and filed in the Investigator Site File and confirmation provided to the CI.
- Any unsuccessful test calls should be documented and patients should not be recruited at that site until successful test call(s) have been completed on all the telephone numbers provided to the patients.

### 7.3. Updates to the Out of Hours Medical Cover Arrangements

- Any changes to the out of hours telephone numbers or staff contact details must be tested prior to implementation.
- The outcome of the test call should be recorded in a trial level file note and filed in the Investigator Site File and confirmation provided to the CI
- All relevant patient documentation must also be updated with the new contact details and provided to all ongoing patients as a matter of priority.

## 8. Monitoring Compliance with and the Effectiveness of this Document

### a. Process for Monitoring compliance and Effectiveness

As part of routine monitoring visits, audit and inspection

### b. Standards/Key Performance Indicators

This process forms part of a quality management system. Documents are reviewed every two years

## 9. References

The Institute of Clinical Research, 2008, Abbreviations used in Clinical Trials.  
ICH GCP

## 10. Associated Documents

Listed in section 5

## 11. Equality and Diversity Statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

## 12. Disclaimer

It is the user's responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

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